UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Carbaglu

| | |
|---|---|
| Program | Prior Authorization |
| Medication | Carbaglu™ (carglumic acid) |
| Markets in Scope | Arizona, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, California, South Carolina |
| Issue Date | 7/2017 |
| Pharmacy and Therapeutics Approval Date | 7/2020 |
| Effective Date | 9/2020 |

## 1. Background:

Carbaglu (carglumic acid) is a Carbamoyl Phosphate Synthetase 1 (CPS 1) activator indicated for maintenance therapy in pediatric and adult patients for chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). Carbaglu is also indicated as an adjunctive therapy in pediatric and adult patients for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS).

## 2. Coverage Criteria:

**A. Initial Authorization**

1. **Carbaglu** will be approved based on the following criteria:

   a. Diagnosis of N-acetylglutamate synthase (NAGS) deficiency

   **Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Carbaglu** will be approved based on the following criteria:

   a. Documentation of positive clinical response to Carbaglu therapy

   **Authorization will be issued for 12 months.**

## 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

## 4. References:


1. Carbaglu [package insert]. Lebanon, NJ: Recordati Rare Diseases, Inc.; December 2019.


| Program | Prior Authorization |
|---|---|
| **Change Control** | |
| Date | Change |
| 7/2017 | New program |
| 7/2018 | Annual review with no change to coverage criteria. Updated reference. |
| 7/2019 | Annual review. Updated reference. |
| 7/2020 | Annual review with no changes to coverage criteria. Added Clinical Rules Section. Updated background and reference. |